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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/721,742	11/26/2003	Masako Nozaki	NOZAKI8.1A	3949

1444 7590 03/16/2006

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EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/721,742	NOZAKI, MASAKO	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-24* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-24 are presented for examination.

Requirement for Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 3, drawn to a method for treating or inhibiting the development of brain edema, comprising administering an effective amount of a leukotriene C4 and D4 receptor antagonist, classified in class 514, subclass 382, for example.

II. Claim 4, drawn to a method for treating or inhibiting the development of stroke, comprising administering an effective amount of a leukotriene C4 and D4 receptor antagonist, classified in class 514, subclass 382, for example.

III. Claims 5-6, drawn to a method for treating or inhibiting the development of brain inflammation due to trauma to the brain, which may result from surgery, classified in class 514, subclass 382, for example.

IV. Claim 7, drawn to a method for treating or inhibiting the development of brain inflammation caused by infection, classified in class 514, subclass 382, for example.

V. Claims 15-20, drawn to a method for treating or inhibiting sepsis, classified in class 514, subclass 382, for example.

VI. Claims 22-24, drawn to methods for screening an inhibitor of increased capillary permeability, classified in class 435, subclass 7.1, for example.

Claims 1-2, 8-14 and 21 link Inventions I-V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-2, 8-14 and 21.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP §804.01.

The inventions are distinct, each from the other, because of the following reasons:

Inventions I through IV are patentably distinct. Inventions are patentably distinct if it can be shown that they have different modes of operation, different functions, or different effects and different resultant endpoints (See MPEP § 806.04, MPEP § 808.01). In the instant case, it is noted that the ultimate therapeutic objective of, for example, Invention I (i.e., treating brain edema) is distinct from the therapeutic objective of, for example, Invention II (i.e., treating stroke), of which each is distinct from the objectives of any one of Inventions III (i.e., trauma to the brain, which may be caused by surgery), IV (i.e., treating or inhibiting the development of brain inflammation caused by infection), V (i.e., treating or inhibiting the development of sepsis) or VI (i.e., screening an inhibitor of increased capillary permeability).

Inventions I through V are held to be patentably distinct because the treatment of any one of Inventions I through V would not necessarily result in the treatment of the other invention.

The patient populations in which each method would be practiced are distinctly different (e.g., patients requiring the treatment of stroke versus patients requiring the treatment of sepsis), such that the treatment of one patient population would not necessarily suggest, anticipate or render obvious the treatment of the other patient population. While there may be incidental overlap in the groups of patients experiencing, for example, stroke, and those experiencing, for example, sepsis, the therapeutic objectives, endpoints and steps required to treat such conditions are vastly different and do not reasonably suggest, anticipate or render obvious the treatment of the other.

Furthermore, the dosage amounts or frequency and route of administration necessary to effect the treatment of patients with, for example, sepsis, would necessarily be independent and distinct from that required for the treatment of patients with, for example, sepsis, due to the differences in etiology of such a condition and the activity of the claimed agent(s) in treating such a condition. Moreover, one skilled in the art could practice the invention of any one of Inventions I through V without practicing the invention of any one of the other inventions. Thus, Inventions I through V are properly considered patentably distinct from one another.

Inventions I-V and VI are held to be patentably distinct because the execution of Inventions I-V would not necessarily result in the execution of Invention VI. The objectives and the steps required to execute such methods are distinctly different from one another, such that there is absolutely no overlap. Thus, a comprehensive search for one of inventions I-V would not necessarily result in a comprehensive search for invention VI. For these reasons, the objectives, endpoints and steps required to execute each of the methods are vastly different and do not reasonably suggest, anticipate or render obvious the execution of the other. The methods are, therefore, patentably distinct.

Because these inventions are distinct for claiming divergent subject matter and the search required for any one of Groups I through VI is not required for any one of the other groups, the inventions are held to be distinct and restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

(a) Causes of sepsis: (vi) Severe Acute Respiratory Syndrome [SARS]; (vii) West Nile Fever; (viii) bacterial food poisoning; (ix) influenza encephalitis; (x) cerebral meningitis; or (xi) arachnoiditis.

(b) Inflammation-inducing agents: (xii) arachidonic acid; (xiii) prostaglandin; (xiv) thromboxane; (xv) histamine; (xvi) LPS; (xvii) dextran; (xviii) bradykinin; (xix) carrageenan; (xx) leukotriene; (xxi) TNF-alpha; (xxii) IL-1β; or (xxiii) IL-6.

The species of conditions resulting in sepsis are independent or distinct because such species are each distinct from one another in etiology, pathophysiological manifestations, treatment protocol (i.e., duration of treatment, dosage amounts of pharmaceutical agents to be administered, frequency of treatment, etc.) and patient population such that a comprehensive search of the patent and non-patent literature for any one such condition would not necessarily result in a comprehensive search of any one or more of the other disorders or conditions recited in the present claims. For example, the treatment of SARS is distinctly different in etiology, pathophysiological manifestation and method of treatment that the prior art related to such a method of treatment would have been sufficiently divergent such that it would not anticipate, suggest or render obvious the treatment of West Nile Fever. Notwithstanding that Applicant may have established an underlying commonality to this broad genus of disorders or conditions, namely, that each may be effectively treated with a leukotriene C4 and D4 receptor antagonist, it

remains that the art does not necessarily recognize such a shared characteristic as being common to each of the variety of conditions encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the conditions contained within the claims, such does not change the fact that each of the conditions are distinct from another because they lack a common etiology, pathophysiological manifestations, treatment protocol and patient population and, therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed conditions would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other conditions of the present claims.

The species of inflammation-inducing agents are independent or distinct because each are structurally, functionally and/or chemically distinct from any one other inflammation-inducing agent recited in the present claims such that a comprehensive search of the patent and non-patent literature for any one such agent would not necessarily result in a comprehensive search of any one or more of the other agents recited in the claims. For example, a reference teaching the use of carrageenan would not necessarily encompass the use of TNF-alpha for the same purpose in light of the fact that each is not recognized to share a structure, function or common status in the art. Notwithstanding that Applicant may have established an underlying common function to a combination of this broad genus of compounds, namely, that they are capable of inducing inflammation, it remains that the art does not necessarily recognize such a shared function as being common to each of the agents encompassed by the claims. Despite the fact that there may be incidental overlap between any one or more of the compounds contained within the claims, such does not change the fact that each of the inflammation-inducing agents encompassed by the claims are distinct from one another because they lack a common physical structure or function

and, therefore, are considered patentably distinct. In addition, the discovery of any one of the presently claimed agents would not necessarily anticipate or reasonably suggest or render obvious any one or more of the other agents of the present claims.

Applicant is required under 35 U.S.C. 121 to elect one of Groups I through VI and a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-2 and 8-24 are generic and will be examined with the elected group/species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, Applicant must indicate which are readable upon the elected species. Please see MPEP §809.02(a).

A telephone call was made to Allen C. Yun at Browdy & Neimark, P.L.L.C. on Monday, March 6, 2006 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should Applicant traverse on the ground that the inventions or species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (8:30 AM-5:00 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571)-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leslie A. Royds
Patent Examiner
Art Unit 1614

March 6, 2006

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